

RECOMBIVAX HB- hepatitis b vaccine (recombinant) injection, suspension
Bamboo US BidCo LLC

RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant)
Suspension for intramuscular injection
Initial U.S. Approval: 1986

These highlights do not include all the information needed to use RECOMBIVAX HB safely and effectively. See full prescribing information for RECOMBIVAX HB.

PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Carton

10 Single-Dose 0.5-mL Syringes

HEPATITIS B VACCINE
[RECOMBINANT]
RECOMBIVAX HB®

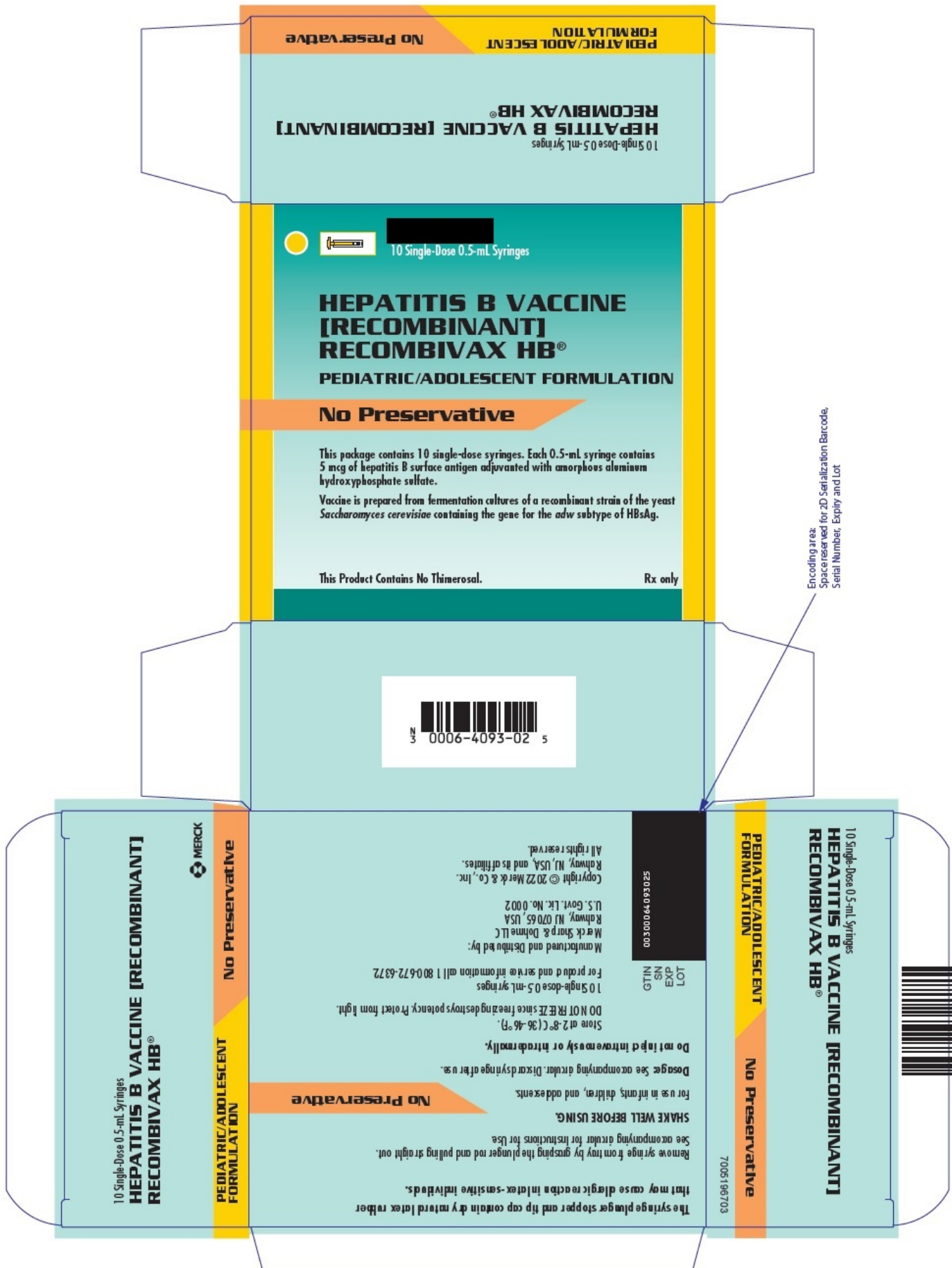
PEDIATRIC/ADOLESCENT FORMULATION

No Preservative

This package contains 10 single-dose syringes. Each 0.5-mL syringe contains 5 mcg of hepatitis B surface antigen adjuvanted with amorphous aluminum hydroxyphosphate sulfate.

Vaccine is prepared from fermentation cultures of a recombinant strain of the yeast *Saccharomyces cerevisiae* containing the gene for the *adw* subtype of HBsAg.

This Product Contains No Thimerosal.
Rx only



FORMULATION PEDIATRIC/ADOLESCENT No Preservative

HEPATITIS B VACCINE [RECOMBINANT] RECOMBIVAX HB®
10 Single-Dose 0.5-mL Syringes

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Encoding area:
Space reserved for 2D Serialization Barcode,
Serial Number, Expiry and Lot

10 Single-Dose 0.5-mL Syringes
HEPATITIS B VACCINE [RECOMBINANT] RECOMBIVAX HB®



No Preservative

PEDIATRIC/ADOLESCENT FORMULATION

No Preservative

The syringe plunger stopper and tip cap contain dry natural rubber that may cause allergic reaction in latex-sensitive individuals.
Remove syringe from tray by grasping the plunger rod and pulling straight out.
See accompanying circular for instructions for use.
SHAKE WELL BEFORE USING.
For use in infants, children, and adolescents.
Dosage: See accompanying circular. Discard syringe after use.
Do not inject intravenously or intradermally.
Store at 2-8°C (36-46°F).
DO NOT REFRIGERATE since freezing destroys potency. Protect from light.
For product and service information call 1 800-672-6372.
Manufactured and Distributed by:
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PEDIATRIC/ADOLESCENT FORMULATION

No Preservative

10 Single-Dose 0.5-mL Syringes
HEPATITIS B VACCINE [RECOMBINANT] RECOMBIVAX HB®



PRINCIPAL DISPLAY PANEL - 1.0 mL Syringe Carton

10 Single-Dose 1.0-mL Syringes

**HEPATITIS B VACCINE
[RECOMBINANT]
RECOMBIVAX HB[®]**

ADULT FORMULATION

No Preservative

This package contains 10 single-dose syringes. Each 1.0-mL syringe contains 10 mcg of hepatitis B surface antigen adjuvanted with amorphous aluminum hydroxyphosphate sulfate.

Vaccine is prepared from fermentation cultures of a recombinant strain of the yeast *Saccharomyces cerevisiae* containing the gene for the *adw* subtype of HBsAg.

**This Product Contains No Thimerosal.
Rx only**

ADULT FORMULATION No Preservative

HEPATITIS B VACCINE [RECOMBINANT] RECOMBIVAX HB® 10 Single-Dose 1.0-mL Syringes

10 Single-Dose 1.0-mL Syringes

HEPATITIS B VACCINE [RECOMBINANT] RECOMBIVAX HB® ADULT FORMULATION

No Preservative

This package contains 10 single-dose syringes. Each 1.0-mL syringe contains 10 mcg of hepatitis B surface antigen adjuvanted with amorphous aluminum hydroxyphosphate sulfate.

Vaccine is prepared from fermentation cultures of a recombinant strain of the yeast *Saccharomyces cerevisiae* containing the gene for the *adw* subtype of HBsAg.

This Product Contains No Thimerosal. Rx only



Encoding area: Space reserved for 2D Serialization Barcode, Serial Number, Expiry and Lot

10 Single-Dose 1.0-mL Syringes
HEPATITIS B VACCINE [RECOMBINANT] RECOMBIVAX HB®



ADULT FORMULATION No Preservative

No Preservative

The syringe plunger stopper and tip cap contain dry natural latex rubber that may cause allergic reaction in latex-sensitive individuals.
For use in adults with the three-dose regimen and in adolescents (11 through 15 years of age) with the alternate two-dose regimen.
Remove syringe from the box by gently pulling the plunger rod and pulling straight out. See accompanying droplet for instructions for use.
SHAKE WELL BEFORE USING.
Dosages: See accompanying circular. Discard syringe after use.
Do not inject intravenously or intradermally.
Store at 2-8°C (36-46°F).
DO NOT FREEZE since freezing destroys potency. Protect from light.
10 Single-dose 1.0-mL syringes
For product and service information call 1 800-672-6372

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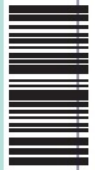
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ADULT FORMULATION

No Preservative

7005195603

10 Single-Dose 1.0-mL Syringes
HEPATITIS B VACCINE [RECOMBINANT] RECOMBIVAX HB®



RECOMBIVAX HB

hepatitis b vaccine (recombinant) injection, suspension

Product Information

Product Type	VACCINE	Item Code (Source)	NDC:83703-085
Route of Administration	SUBCUTANEOUS, INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN (UNII: XL4HLC6JH6) (HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN - UNII:XL4HLC6JH6)	HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN	5 ug in 0.5 mL

Product Characteristics

Color	white (slightly opaque, white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-085-02	0.5 mL in 1 SYRINGE; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101066	02/26/2026	

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hepatitis b vaccine (recombinant) injection, suspension

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Ingredient Name	Basis of Strength	Strength
HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN (UNII: XL4HLC6JH6) (HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN - UNII:XL4HLC6JH6)	HEPATITIS B VIRUS SUBTYPE ADW HBSAG SURFACE PROTEIN ANTIGEN	10 ug in 1 mL

SURFACE PROTEIN ANTIGEN - UNII:XL4HLC6JH6)	PROTEIN ANTIGEN	III I III
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Product Characteristics

Color	white (slightly opaque, white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83703-086-02	1 mL in 1 SYRINGE; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA101066	02/26/2026	

Labeler - Bamboo US BidCo LLC (119087615)

Revised: 3/2026

Bamboo US BidCo LLC